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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/015,631

12/10/2001

Jesse J. Kuhns

END-786

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04/20/2006

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EXAMINER

NGUYEN, TUAN VAN

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/015,631

Applicant(s)

KUHNS ET AL.

Examiner

Tuan V. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-15, and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-17 were examined and rejected in Office Action mailed out on October 5, 2005. According to the Response Non-Final Rejection applicant filed on February 01, 2006. Applicant amended claims 1, 9 and 10-17 to overcome the rejections therefore objections to claims 1, 9 and 10-17 are withdrawn.
2. Applicant filed Terminal Disclaimer and it was approved by the USPTO therefore double patenting rejection is withdrawn.
3. Applicant cancelled claims 8 and 16. Now claims 1-7, 9-15, and 17 are pending in this application.

Response to Amendment

4. Applicant's arguments filed on February 01, 2006 with respect to claims 1-7, 9-15, and 17 have been fully considered but they are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the

international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **Claims 1, 5-7, 9, 13-15, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in alternative, under 35 U.S.C. 103 (a) as obvious by Miller et al (U.S. 6,709,442).**
7. Referring to claims 1 and 9, Miller discloses a surgical fastener system (see Figs. 34-38) for delivering a plurality of surgical fasteners comprising: a drive mechanism having distal and proximal ends, drive mechanism comprising a needle assembly 230 or moving member wherein the needle assembly includes needle head 232 and suture element 236 or fastener, and push element 238; and a sleeves 218, 224, and flange 226 or fixed opposing member includes flange 228 and 220, an actuator 210 includes stop detent 244, lever 256. The actuator having at least two sequential positions, first position for moving needle assembly 230 distally and piercing tissue, and a second position for moving needle assembly 230 proximally, thereby deploying said distal end of said fastener; and a mechanism includes slot 248a, 248b for receiving detent or protrusion 254 on needle assembly 230 which prevents actuator from moving to said second position, after initially moving to first position, until actuator has fully moved to its first position, and from moving to said first position, after initially moving to said second position, until said actuator has fully moved to its second position (see col. 12, line 50 to col. 13, line 20).

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8. Referring to claims 5 and 13, Miller discloses the surgical fastener can be made from any material so long as it is adequately elastic (see col. 6, lines 1-5). Here it is noted that surgical fastener formed from stainless steel is well known in the art.
9. Referring to claims 6, 7, 14, and 15, Miller discloses the fastener is made from super-elastic alloy of nickel titanium (see col. 5, lines 53-68).
10. Referring to claim 17, it is rejected for the same reason as claim 9.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al (U.S. 6,709,442) further in view of Wenstrom (U.S. 6,007,566).

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14. Referring to claims 3, Miller discloses the inventions substantially as claimed except for the fasteners includes at least one barb extending axially away from said distal end, and one barb extending axially away from said second end. Wenstrom discloses a fastener (see Figs. 1 and 2) includes at least one barb 32 extending axially away from said distal end, and one barb extending axially away from said second end 40.
15. Still referring to claim 3, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the fastener, as disclosed by Wenstrom, to incorporate into the device, as disclosed by Miller because this will provide more anchoring force per fastener.
16. **Claims 2, 4, 8, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al (U.S. 6,709,442) further in view of Wenstrom (U.S. 6,007,566) and further in view of McGarry et al (U.S. 4,509,518).**
17. Referring to claim 2, Miller discloses the inventions substantially as claimed except for the moving and fixed members have inner surfaces having a plurality of projections spaced thereon, said projections engaging said fasteners; the barbs engage inner surfaces of moving and fixed member. McGarry et al disclose an apparatus for applying surgical clips to tissue (see Figs. 2 and 12-14) includes a moving member 92 and fixed member 94 having inner surfaces having a plurality of projections 102 and 104, respectively, spaced thereon, and projections engaging fasteners 36. Wenstrom discloses a tissue fastener substantially as claimed.

18. Still referring to claim 2, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the fastener delivery device, as disclosed by McGarry et al, to incorporate into the device, as disclosed by Wenstrom, then to incorporate into the device, as disclosed by Miller because this will provide surgeon the ability to apply more anchoring devices to target site without reloading the applicator.
19. Claims 4, 8, and 16 are rejected for the same reason as claim 2.
20. **Claims 1, 5-7, 9, 13-15, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in alternative, under 35 U.S.C. 103 (a) as obvious by Miller (U.S. 6,837,893).**
21. Referring to claims 1 and 9, Miller discloses a surgical fastener system (see Figs. 5A-5C) of individual surgical fasteners comprising: a drive mechanism having distal and proximal ends, drive mechanism comprising a needle 54 or moving member and a sleeve 51 or fixed opposing member, moving member having a sharpened distal end for piercing tissue; at least one surgical fastener 10, each of one surgical fasteners having a proximal end and a distal end; an actuator (head 60 and plunger 52) having at least two sequential positions, first position (see Fig. 5B) for moving said moving member distally and piercing tissue, and a second position (see Fig. 5C) for moving said moving member proximally, thereby deploying said distal end of said fastener; and a mechanism (stops 62 and 64) which prevents actuator from moving to said second position, after initially moving

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to first position, until actuator has fully moved to its first position, and from moving to said first position, after initially moving to said second position, until said actuator has fully moved to its second position (see Figs. 5B and 5C). Miller also discloses an alternative embodiment (see Figs. 10-12A) a surgical fastener system for delivery of multiple fasteners comprising a fixed member includes handle 235, body 220, and cartridge 215; moving member 230 and 210; a plurality of elastically constrained surgical fasteners located between fixed and moving members, wherein the fasteners are not engaging one another and are spaced apart from one another (see col. 12, lines 14-56). It would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to combined the design of Figs 5A-5F with the design of Figs 10-12A into one because this will provide a delivery device having capability of delivering a plurality of surgical fasteners and having a mechanism which prevents the actuator from premature delivered the fastener before the penetration of tissue is completed.

22. Referring to claims 5 and 13, Miller discloses the surgical fastener can be made from any material so long as it is adequately elastic (see col. 7, lines 25-29). Here it is noted that surgical fastener formed from stainless steel is well known in the art.
23. Referring to claims 6, 7, 14, and 15, Miller discloses the fastener is made from super-elastic alloy of nickel titanium (see col. 7, lines 10-20).
24. Referring to claim 17, it is rejected for the same reason as claim 9.

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25. **Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller (U.S. 6,837,893) further in view of Wenstrom (U.S. 6,007,566).**
26. Referring to claims 3, Miller discloses the inventions substantially as claimed except for the fasteners includes at least one barb extending axially away from said distal end, and one barb extending axially away from said second end. Wenstrom discloses a fastener (see Figs. 1 and 2) includes at least one barb 32 extending axially away from said distal end, and one barb extending axially away from said second end 40.
27. Still referring to claim 3, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the fastener, as disclosed by Wenstrom, to incorporate into the device, as disclosed by Miller because this will provide more anchoring force per fastener.
28. **Claims 2, 4, 8, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller (U.S. 6,837,893) further in view of Wenstrom (U.S. 6,007,566) and further in view of McGarry et al (U.S. 4,509,518).**
29. Referring to claim 2, Miller discloses the inventions substantially as claimed except for the moving and fixed members have inner surfaces having a plurality of projections spaced thereon, said projections engaging said fasteners; the barbs engage inner surfaces of moving and fixed member. McGarry et al disclose an apparatus for applying surgical clips to tissue (see Figs. 2 and 12-14) includes a moving member 92 and fixed member 94 have inner surfaces having a plurality

projections 102 and 104, respectively, spaced thereon, and projections engaging fasteners 36. Wenstrom discloses a tissue fastener substantially as claimed.

30. Still referring to claim 2, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the fastener delivery device, as disclosed by McGarry et al, to incorporate into the device, as disclosed by Wenstrom, then to incorporate into the device, as disclosed by Miller because this will provide surgeon the ability to apply more anchoring devices to target site without reloading the applicator.
31. Claims 4, 8, and 16 are rejected for the same reason as claim 2.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen
April 10, 2006



ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

4/15/06